UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

IN RE: VALSARTAN PRODUCTS LIABILITY LITIGATION **This Document Relates to All Actions**	MDL No. 2875 Honorable Robert B. Kugler, District Judge Honorable Joel Schneider, Magistrate Judge

AGENDA FOR MAY 29, 2019 CASE MANAGEMENT CONFERENCE

The parties hereby submit this joint agenda in advance of the May 29, 2019 Case Management Conference.

1. Streamlined Service Protocol

Plaintiffs' Position:

Plaintiffs presented the concept of a streamlined service protocol to Defendants, and are vetting platforms for this purpose. It is plaintiffs' understanding that Defendants are agreeable to a centralized system for service on all Defendants.

Defendants' Position:

Defendants have not received a streamlined service protocol proposal from the Plaintiffs. However, as previously indicated, Defendants expect the parties will reach agreement on such a protocol.

2. Master Complaints

Plaintiffs' Position:

Plaintiffs proposed a process whereby the Master Complaints would be provided to the defense in advance of filing. Plaintiffs proposed a deadline of June 17, 2019 for circulating the master complaints to Defendants. The Plaintiffs also proposed that by June 24, 2019, the Defendants provide any comments on factual inaccuracies and other pleading issues apparent to the defense in order to avoid unnecessary motion practice, and to allow the parties to preview any issues with Judge Schneider during the June 26, 2019, hearing. Defendants have indicated that they need additional time to review the Master Complaints. Plaintiffs are not

opposed to ensuring a reasonable amount of time is provided but believe 45 days to be more than necessary. The parties will continue to confer on this issue.

Defendants' Position:

Plaintiffs have proposed that the Master Complaints be circulated to Defendants before they are filed, and that Defendants would have seven days to identify inaccuracies or issues that may otherwise lead to motion practice. Defendants are not opposed to reviewing the Master Complaints in some fashion before they are filed. However, the scope of that review should be specifically defined by the Court, and should be narrowly tailored so as not to preclude Defendants from filing Rule 12 motions that are issue or claim dispositive or otherwise warranted, and which Defendants believe cannot be cured by Plaintiffs' pleading of any plausible set of facts. In addition, seven days is far too few for the 40 or so defendants to review and organize their comments to three master complaints that took more than four months to draft. Defendants suggest 45 days for such review, if any is ordered.

3. Short Form Complaints

Plaintiffs' Position:

Plaintiffs will shortly be providing a proposed Short Form Complaint to the defense.

Defendants' Position:

Claims set forth in Master Complaints that survive dismissal, if any, should be deemed to be denied by Defendants in accordance with this Court's Case Management Order No. 2. *See* Dkt. 72 at 2. Individual Plaintiffs should then file Short Form Complaints setting forth Plaintiff's state of residence and specific facts supporting their individual claims in a manner to be agreed upon between the parties or determined by the Court. Consistent with Case Management Order No. 2, individual answers to Short Form Complaints are also unnecessary, as all allegations therein will be deemed denied unless otherwise stated.

4. Stipulation for Dismissal of Peripheral and Minor Defendants

Plaintiffs' Position:

The parties are in the process of negotiating a Stipulation and expect to reach agreement. Plaintiffs must ensure that there is no prejudice through this process, including access to necessary information and documents, the ability to easily bring these defendants into the active litigation if warranted, and tolling – both for filed cases and cases to be filed in the future.

Defendants' Position:

The parties have exchanged three drafts of the proposed Stipulation that would be utilized to dismiss the tangential Defendants, and have engaged in several substantial and productive meet-and-confers. The parties have agreed thus far to the following: 1) any Defendant as to which it is determined that dismissal is appropriate will be able to utilize the Stipulation to achieve dismissal; 2) dismissal would be without prejudice; 3) the Stipulation will require the Defendant to make certain disclosures as a pre-condition of their dismissal; 4) any disputes over the sufficiency of the disclosures will be resolved by the Court following a meet-and-confer; and 5) the Stipulation will also require the Defendant to agree to a tolling agreement that will apply to every currently filed action within the MDL and (as of the date notice is provided to the Defendant) to every future valsartan claim later transferred into the MDL.

The parties are still negotiating over the scope of the required disclosures and the selection of Defendants who will be entitled to dismissal. The Defendants' position is that the procedure should be utilized to narrow the Defendants in the case to the API and finished-dose manufacturers, and that the remaining Defendants should be required as part of the procedure to produce no more than is minimally necessary for Plaintiffs to prosecute their case against the remaining parties. The parties also are still discussing the proper language needed to effectuate their agreement in principle regarding tolling. Defendants are optimistic that all of the outstanding issues can be resolved before the next in-person conference.

5. Defendants' Insurance Information

Plaintiffs' Position:

Plaintiffs look forward to receiving the ordered insurance information.

Defendants' Position:

The pertinent Defendants will produce to Plaintiffs insurance information in accordance with the Court's May 6, 2019 Order. *See* Dkt. 98.

6. ESI Protocol

Plaintiffs' Position:

The negotiations of the ESI protocol have been intensive and it is expected that the protocol will be agreed to prior to the case management conference. To the extent that provisions are not agreed to, competing versions will be submitted to the Court in a single redline on May 28, 2019. Plaintiffs also requested information regarding the Defendants' maintenance of ESI in order to avoid a 30(b)(6) deposition and Defendants have refused to engage in this information exchange. Plaintiffs will seek the Court's direction that the Defendants agree to

engage in this informal meet and confer process, or provide a 30(b)(6) representative in the alternative. The parties will submit these requests to the Court on May 28, 2019 with the other submissions.

Defendants' Position:

The parties are close to finalizing an ESI Protocol, which is based largely on the protocol adopted in the Benicar litigation. To date, the parties have exchanged six substantive drafts and have engaged in multiple productive meet-and-confers. The parties are presently negotiating a small handful of remaining issues, which they expect to resolve before the case management conference. In the event that any issues are not resolved in time, the parties will identify them to the Court by Tuesday, May 28, pursuant to the Court's Order (ECF 88).

As for Plaintiffs' ESI discovery demands, the Court has already rejected them, indicating that there is no need to take "discovery on discovery." Such additional discovery would be unduly burdensome on all parties, especially the peripheral defendants.

7. Plaintiffs' Initial Profile Forms

Plaintiffs' Position:

Defendants provided redlines of the proposed profile forms during the week of May 20, and the parties have been conferring to resolve the form of this exchange, and impact on the scope and use of full Plaintiff Fact Sheets. Plaintiffs proposed a process whereby the profile forms would be served within 60 days of filing a complaint, providing the core information required by the parties and the Court to understand the scope of the cases in the litigation. Plaintiffs agreed that all plaintiffs completing a profile form would provide product identification, including pharmacy records, and personal injury plaintiffs would provide verifications and medical authorizations for the key treating medical providers identified in the profile form, including prescribing physicians of Valsartan, physicians who diagnosed the plaintiff's cancer, and the medical providers who treated the cancer. These records will be sufficient to understand a plaintiff's full medical and surgery history, medication history, all pre-existing medical conditions, and the full diagnosis and treatment history for the plaintiff's cancer. In return for providing this extensive core information, verified and with authorizations, Plaintiffs sought agreement that only those plaintiffs selected for bellwether work up would complete full blown Plaintiff Fact Sheets, saving the parties substantial time (not having to prepare and receive this extensive information for cases that are unlikely to ever approach a trial setting), and the substantial expense of obtaining the full scope of relevant documents and records. Defendants considered and rejected this proposal, requesting two layers of extensive disclosures, which is inefficient and will not substantially advance the parties' knowledge of the key facts since those will all be disclosed in the Plaintiffs' proposed profile forms.

Variations have been proposed for the economic reimbursement class plaintiffs and it is hoped that those may be resolved prior to the conference. Plaintiffs will submit proposed forms of each profile form on May 28, 2019.

Defendants' Position:

The parties exchanged redlines and continue to meet and confer over the proposed Plaintiff Profile Forms. The parties agree on the majority of the content currently requested in the Plaintiff Profile Forms and will be prepared to present the remaining disputed issues at the case management conference. The primary unresolved issues relate to process, rather than content, and specifically the need for (1) verification; (2) a show cause process; and (3) signed authorizations for the collection of medical, pharmacy and insurance records.

Defendants believe that in order to ensure accurate, actionable information which parallels the core discovery Defendants are currently producing, the Profile Forms should be verified. At this time there are a small number of Plaintiffs, and the burden on these parties and their counsel of having to review and verify the information in the Profile Forms is minimal.

Additionally, Defendants request that the Court implement a show cause process governing non-compliance and deficiencies similar to that used by this Court in *Benicar*. The proposed process ensures that a non-complying Plaintiff's complaint will be dismissed only following due process, including written notice and three consecutive in-person case management conferences where the case is identified as deficient on the agenda. This process satisfies due process requirements of notice and hearing, ensures these deficiencies are addressed timely, and promotes judicial economy in eliminating the need for motions practice. Judge Schneider suggested the parties consider just such a process during the last teleconference.

Furthermore, personal injury and consumer class representative Plaintiffs should be required to execute authorizations for medical, pharmacy, and health insurance records and to provide said authorizations along with their Profile Forms. These records are essential to demonstrating proof of use and proof of injury and will aid the parties and the Court in early identification and disposition of cases lacking product ID.

Plaintiff has indicated they will agree to verification, the show cause process, and authorizations only if Defendants agree that full Plaintiff Fact Sheets will be reserved until the time of bellwether selection. Defendants cannot agree to this proposal for a variety of reasons, which Defendants will be prepared to address. For example, the Fact Sheet information is needed in order to aid in early assessment and vetting of Plaintiffs' claims. Moreover, upon information and belief, certain of these Plaintiffs may be terminal and delaying Plaintiff Fact Sheets will jeopardize the parties' ability to collect necessary discovery and information from these Plaintiffs. Likewise, there is a risk that medical records and other evidence may be lost over the passage of time if full Fact Sheets and/or

authorizations are delayed until bellwether time. The current number of Plaintiffs – fewer than 50 spread over multiple Plaintiffs' counsel – is not so voluminous that it would create an unreasonable burden. A similar two-tiered process, whereby Plaintiffs executed verified Profile Forms at an initial stage of the case, and verified Plaintiff Fact Sheets at a later stage, has been utilized in a number of other MDLs. See, e.g., MDL No. 2387 - *In Re Coloplast Corp. Pelvic Support Systems Products Liability Litigation*; MDL No. 2187 - *In Re C. R. Bard, Inc., Pelvic Repair System Products Liability Litigation*; MDL No. 2325 - *In Re American Medical Systems, Inc., Pelvic Repair System Products Liability Litigation*; and MDL No. 2327 - *In Re Ethicon Inc., Pelvic Repair System Products Liability Litigation*. Plaintiffs' counsel proposed the use of Profile Forms, and until the most recent teleconference with Judge Schneider had not raised the possibility of not also preparing full Plaintiff Fact Sheets. Defendants strongly oppose limiting the Profile Forms in such a way that they do not provide verifiable information and enable the parties to actively vet the cases which have been filed.

Following the conclusion of the parties' ongoing meet and confer efforts, but prior to the scheduled case management conference, Defendants anticipate submitting drafts of their three proposed Plaintiff Profile Sheets (personal injury, consumer class action, and third-party payer).

8. Discovery Confidentiality Order

Plaintiffs' Position:

Defendants provided their response to Plaintiffs' redline of the proposed Order during the week of May 20. The parties have begun to confer, and Plaintiffs are hopeful that a minimum number of issues will be presented to the Court for resolution. Based on the current status of the discussions, one issue the Court will have to determine is the process for challenge to confidentiality designations. Plaintiffs have adopted the process from the Benicar MDL: (1) written challenge to designations, (2) meet and confer within a reasonable period of time, (2) if the challenge is not resolved, the designating party is to file a motion to maintain the designation or the designation is waived. Defendants want to require a Court Order to invalidate a designation, which is burdensome on the parties, especially the challenging party, and the Court, and inefficient since the designating party will in almost every instance decide not to file the motion and the designation will be withdrawn by operation of the Discovery Confidentiality Order. Similarly, Plaintiffs seek inclusion of a phrase taken directly from the Benicar Order, reciting the potential for sanctions in the event of over-designation, and Defendants disagree.

The parties are continuing to discuss multiple provisions, and have resolved most of the issues, while identifying a small handful of issues for the Court's consideration. The parties will submit the competing language in a single redline on May 28, 2019 to the extent agreement is not reached.

Defendants' Position:

The parties continue to discuss issues pertaining to the Discovery Confidentiality Order and had a very productive conference on May 23rd. The parties will continue to meet and confer and intend to submit competing orders identifying the unresolved areas of conflict prior to the case management conference, so that the Court may resolve these outstanding issues.

One known irreconcilable area of dispute relates to the process for resolving challenges to confidentiality designations. Plaintiff have proposed a process that could result in the loss of confidentiality to designated documents simply due to the passage of time, even without a court order. Defendants advocate for a process that allows continuation of a confidentiality designation, even in the face of a challenge, unless or until the Court issues its determination on the challenge. Defendants' proposal allows for *either side* to file a motion with the Court to resolve any dispute over a designation. Plaintiff's proposal puts all the burden on Defendants. Plaintiff's proposal therefore presents a substantial risk that confidentiality could be unintentionally waived while the parties are conferring or due to excusable oversight, and such a penalty would be unnecessarily harsh. Additionally, Plaintiffs' proposal could result in an unnecessary increase in the volume of motions given the rush to file for fear of waiver. Although the process may have differed in *Benicar*, there are a larger number of defendants, a larger number of documents that will be exchanged, and a greater risk of harm. Therefore, Defendants' process, which has been endorsed by many other federal courts in MDLs and otherwise, is the more reasonable approach.

The parties will continue to meet and confer, and will identify any additional areas that need the Court's resolution at or before the case management conference.

9. Core Discovery

Plaintiffs' Position:

Plaintiffs look forward to receipt of the core discovery ordered by the Court. To the extent a U.S. subsidiary of a foreign entity claims it has no ability to produce documents from a foreign parent, discovery will unfortunately be necessary on that issue unless the foreign entity can be timely brought into the litigation.

Defendants' Position:

The pertinent Defendants have been working with their clients to compile the information responsive to the Order on Core Discovery dated April 29, 2019. *See* Dkt. 88. These Defendants expect to produce ANDAs, Drug Master Files, and recall communications by the June 17, 2019 deadline, subject to entry of the Discovery Confidentiality Order, but may need additional time to produce documents responsive to Paragraph 6(a)(3)(5) of the Court's April 29, 2019

Order. Defendants propose producing these additional documents on a rolling basis within 45 days of June 17.

Aurobindo Pharma USA, Inc. and AuroLife Pharma LLC have been working with their counsel to compile the information responsive to the Order on Core Discovery and expect to produce the ANDA files for each involved finished dosage formulation and the recall communications by the June 17, 2019 deadline, but may need additional time to produce documents responsive to Paragraph 6(a)(3)(5) of the Order. Aurobindo Pharma USA, Inc. and AuroLife Pharma LLC agree with the foregoing proposal to produce these additional documents on a rolling basis within 45 days of June 17. Items relating to API manufacturing are not available to Aurobindo Pharma USA, Inc. or AuroLife Pharma LLC. Those documents belong to Aurobindo Pharma Ltd. located in Hyderabad, India. Aurobindo Pharma Ltd. has not been served in any action and is not represented by counsel. It is possible that counsel for Aurobindo Pharma USA, Inc. and AuroLife Pharma LLC may not represent Aurobindo Pharma Ltd. in this litigation.

Hetero USA, Inc. (Hetero USA) is neither an API or finished dose manufacturer for core discovery. However, at the request of the court, Hetero USA, Inc. is working with its counsel to compile the information it has in its possession which is responsive to the Order on Core Discovery and expects to produce the ANDA file of the involved finished dosage formulation, as well as that portion of the DMF file included therein by the June 17, 2019 deadline. In addition, to the extent in its possession, Hetero USA will produce recall communications; however, Hetero USA will likely need additional time to produce same. Hetero USA does not have the remaining categories of core discovery documents set forth in the order. Items relating to API manufacturing are not in Hetero USA's possession. Those documents belong to Hetero Labs Limited (Hetero Labs) located in Hyderabad, India. Upon information and belief, Hetero Labs has not been served in any action and is not represented by counsel. Counsel for Hetero USA does not presently represent Hetero Labs and has no indication it will represent Hetero Labs in this litigation. Nonetheless, we are advised that Hetero USA is continuing discussions with Hetero Labs to explore the production of core discovery documents which are not in Hetero USA's possession.

10. Document Repository

Plaintiffs' Position:

Plaintiffs are nearly ready to retain a vendor, and will have the repository in place for receipt of the core discovery productions.

Defendants' Position:

Defendants continue to vet document repository companies for coordination of Defendants' discovery productions. Defendants have received several quotes

from competing vendors and are currently reviewing the proposals. Defendants expect that the repository will be ready in advance of the June 17, 2019 core discovery deadline.

11. Coordination of Related Cases

Plaintiffs' Position:

Plaintiffs are aware of a small handful of state court cases, as listed by the Defendants. Plaintiffs are coordinating with counsel in the New Jersey cases at present.

Defendants' Position:

There are currently six actions pending outside the MDL that are virtually identical to the cases within the MDL. These cases should be coordinated with the MDL for pretrial purposes. *See* Manual for Complex Litigation (Fourth) § 20.31; *see also id.* at § 22.4 (federal and state judges "frequently coordinate informally and effectively to coordinate discovery and pretrial proceedings in mass tort cases"); *In re Diet Drugs Prods. Liab. Litig.*, MDL No. 1203, 1999 WL 124414, at *1 (E.D. Pa. Feb. 10, 1999) ("state/federal coordination of discovery and other pre-trial activities will be in the best interest of the parties named in the cases under their respective jurisdictions, as well as the public interest where it is affected by those cases."); *see also* Tr. of Apr. 24, 2019 Status Conference at 11:9-10 ("I can't imagine why [discovery] would be different, but there's no sense in doing it twice."). Indeed, Judge Kugler has already expressed a desire to coordinate with judges presiding over related cases. *See* Tr. of Apr. 24, 2019 Status Conference at 10:15-17. A chart with the judges' contact information is attached as Exhibit A.

Defendants have proposed coordinated schedules to plaintiffs' counsel in these actions, without success. Defendants respectfully request that the Court contact the judges presiding over these actions—especially *Runo*, *Orlowksy*, and *Shanov*—to facilitate coordination, including the entry of a joint coordination order that provides, among other things: (1) that the MDL proceeding is the lead case for discovery and pretrial scheduling; (2) that all discovery and pretrial scheduling should be coordinated to the fullest extent possible with the MDL proceeding; (3) that counsel in the state actions are entitled to receive discovery taken in the MDL proceeding, provided that such discovery responses and documents are used and disseminated only in accordance with the terms of the MDL Discovery Confidentiality Order; and (4) that parties in the state actions may take additional discovery only upon leave of the court in which the state action is pending. The joint coordination order should also establish procedures for how plaintiffs' counsel in the state actions can participate in discovery requests and depositions propounded within the MDL proceeding.

The related actions are:

- *Runo v. Prinston Pharmaceutical Inc.*, No. MID-L-00856-19 (N.J. Super.) and *Orlowsky v. Solco Healthcare U.S., LLC*, No. MID-L-0002554-19 (N.J. Super.):

  These are valsartan personal injury actions that are not removable. The parties agree that these two actions should be consolidated and have moved for consolidation. Plaintiffs in both actions are represented by the same counsel, who is also a member of Plaintiffs' leadership in this MDL. On May 9, Judge Schneider ordered plaintiff's counsel in these cases to attend the May 29 conference to discuss coordination. *See* Dkt. 103.

- *Shanov v. Walgreens Co.*, No. 2018-CG-15272 (Cook Co. Cir. Ct., Illinois):

  This is a valsartan economic loss class action. Defendants have moved to join diverse defendant Solco Healthcare U.S., LLC and anticipate removing this case and transferring it to the MDL once that motion is decided. The judge presiding over this case has indicated that a backlog will prevent her from deciding the motion until at least August.

- *Collins v. Prinston Pharmaceutical Inc.*, No. 3:19-cv-00415 (S.D. Cal.) and *Collins v. Aurobindo Pharma USA, Inc.*, No. 3:19-cv-0688 (S.D. Cal.):

  These cases are economic loss class actions filed on behalf of a California class. Defendants removed them from state court in April, 2019 and then requested transfer to this MDL. The JPML has issued conditional transfer orders for both actions, which the plaintiff opposes. Briefing on whether transfer is appropriate is underway. Defendants anticipate that the JPML will order transfer.

- *Wineinger v. Solco Healthcare U.S., LLC*, No. 19-1070 (D. N.J.):

  This is an economic loss class action. It involves only irbesartan and is therefore outside the scope of the MDL. On May 3, 2019 Judge Freda L. Wolfson granted the parties' joint request for an intra-district transfer under 28 U.S.C. § 1404(b). *Wineinger* is now pending before Judge Kugler and Judge Schneider for coordination with the MDL. The parties have agreed that all deadlines are suspended until further instruction.

12. Inclusion of Losartan and Irbesartan

Plaintiffs' Position:

Plaintiffs expect Losartan cases to continue to be filed, and when an appropriate number are on file, an application will be filed with the JPML to consolidate those

cases into this MDL. This application is not imminent, but is expected to be filed in 2019.

Defendants' Position:

Because there are a limited number of cases related to impurities found in losartan and irbesartan pending, Defendants maintain that it is premature to move the JPML to include those drugs in the MDL. Defendants reserve the right to so move the JPML (or to oppose such a motion), based on future developments. There are a few non-valsartan Defendants that may oppose transfer should it be sought in the future, including on the basis that some entities have recalled only small amounts of product and have *de minimis* exposure that does not justify transfer.

At the same time, Defendants recognize the likelihood of efficiencies of coordination of the irbesartan and losartan cases with the MDL. As noted in Agenda Item No. 11 above, *Wineinger v. Solco Healthcare U.S., LLC*, No. 19-1070, involves irbesartan and is now pending before this Court for coordination with the MDL in all proceedings.

Dated: May 24, 2019

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CERTIFICATE OF SERVICE

A true and correct copy of the foregoing was served this 24th day of May, 2019 on all counsel of record via the CM/ECF system of the United States District Court for the District of New Jersey.

/s/ Seth A. Goldberg
Seth A. Goldberg